

### ***Remarks***

#### ***I. Status of the Claims***

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 38-143 are pending in the application, with 38, 73, 102, 103 and 113 being the independent claims. Claims 38, 52, 53, 60, 67 and 68 have been amended. Claims 39 and 73-109 are canceled without prejudice or disclaimer. New claims 110-145 are sought to be added. Claims 1-37 were previously canceled without prejudice or disclaimer. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

#### ***II. The Amendments***

The pending claims are directed to methods for treating or reducing the risk of allergic disease or non-allergic inflammatory disease in a mammal through administration of an extract of hardy kiwifruit. In one embodiment, the hardy kiwifruit is selected from the group consisting of: *Actinidia arguta*, *Actinidia kolomikta* and *Actinidia polygama*. In another embodiment, allergic disease is selected from the group consisting of: anaphylaxis, allergic rhinitis, asthma, allergic conjunctivitis, urticaria, insect allergy, food allergy and drug allergy and non-allergic inflammatory disease is selected from the group consisting of: systemic lupus erythematosus, retinal inflammation, gastritis, retinopathy, hepatitis, enteritis, pancreatitis and nephritis

Claim 38 has been amended to recite only extracts of hardy kiwifruit species: *Actinidia arguta*, *Actinidia kolomikta*, and *Actinidia polygama*. Support for this amendment can be found in the specification on page 5, lines 23-27 and page 6, lines 31-32. Claim 38 has also been amended to recite "for treating or reducing the risk of" in place of "to treat or prevent." Support for this amendment can be found in the specification on page 4, lines 10-12; page 5, lines 18-27; page 8, lines 29-32; and Experimental Example 6.

Claim 52 has been amended for clarity and now recites "diluting the crushed and dried hardy kiwifruit in a volume of water in a ratio from about 1:5 to about 1:25." Support for this amendment can be found in the specification on page 7, line 21. Claim 53 has also been amended for clarity and now recites "diluting the crushed and dried hardy kiwifruit in a volume of lower alcohol in a ratio from about 1:5 to about 1:25." Again, support for this amendment can be found in the specification on page 7, line 21.

Claims 60, 67 and 68 have been amended to recite "reduce the risk of" in place of "prevent." Support for these amendments can be found on page 4, lines 10-12; page 5, lines 18-27; page 8, lines 29-32; and Experimental Example 6.

New claims 113-145 are directed to methods for treating or reducing the risk of allergic disease or non-allergic inflammatory disease in a mammal, comprising administering an extract of hardy kiwifruit to the mammal in an amount sufficient to treat or reduce the risk of at least one symptom of allergic disease or non-allergic inflammatory disease in the mammal, wherein the allergic disease is selected from the group consisting of: anaphylaxis, allergic rhinitis, asthma, allergic conjunctivitis, urticaria, insect allergy, food allergy and drug allergy and wherein the non-allergic

inflammatory disease is selected from the group consisting of: systemic lupus erythematosus, retinal inflammation, gastritis, retinopathy, hepatitis, enteritis, pancreatitis and nephritis.

Support for the new claims can be found *inter alia* in the disclosure as follows:

CLAIM	SUPPORT
110, 111, 112, 114	See, for example, page 5, lines 23-27; and page 6, lines 31-32.
113, 135, 136	See, for example, page 5, line 23-27; page 6, lines 5-7; and page 6 lines 27-29.
115	See, for example, page 6, lines 31-32.
116	See, for example, page 5, lines 18-21.
117, 118, 119	See, for example, page 6, lines 34-37; and page 7, line 1.
120	See, for example, page 13, line 5.
121	See, for example, page 8, lines 34-36.
122	See, for example, page 10, lines 1-9.
123, 124, 125	See, for example, Experimental Example 7.
126, 127, 128, 129, 130, 131, 132, 133, 134	See, for example, page 7, lines 20-32; and Example 1.
137	See, for example, page 9, lines 1-3.
138	See, for example, page 9, lines 27-31.
139, 142, 143, 144, 145	See, for example, page 9, lines 9-10; page 10, lines 26-29; page 12, lines 3-4; and page 12, lines 19-25.
140, 141	See, for example, page 13, lines 13-16.

Accordingly, no new matter is believed to have been added by the amendments, and their entry is respectfully requested.

**III. The Rejections**

**A. Rejections Under 35 U.S.C. § 112**

The Examiner has rejected claims 38-72 under 35 U.S.C. § 112, first paragraph, for allegedly failing to "enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims." (Office Action of January 3, 2007, page 3.) Specifically, the Examiner has stated that:

the specification, while being enabling for a method to treat allergic disease or non-allergic inflammatory disease in a mammal, does not reasonably provide enablement for a method to prevent such diseases.

(Office Action of January 3, 2007, page 3.) Applicants respectfully disagree and submit that the specification adequately enables both methods of treating and methods of preventing allergic disease and non-allergic inflammatory disease. However, without acquiescing in the rejection, and solely to advance prosecution, Applicants have amended claims 38, 60, 67 and 68 to replace the term "prevent" with the phrase "reduce the risk of" and the phrase "to treat or prevent" with the phrase "for treating or reducing the risk of." The amended claims now recite a method for treating or reducing the risk of allergic disease or non-allergic inflammatory disease. Support can be found for the claim amendments in the specification on page 4, lines 10-12; page 5, lines 18-27; page 8, lines 29-32; and Experimental Example 6. Experimental Example 6 specifically shows that hardy kiwifruit extract application can inhibit or reduce the risk of inflammation and edema caused by the application of arachidonic acid, a known irritant. As the claims no longer recite preventing, Applicants believe the Examiner's rejection to be moot. Reconsideration and withdrawal of the rejection is respectfully requested.

**B. Rejections Under 35 U.S.C. § 102**

The Examiner has rejected claims 38, 40, 45-59, 62 and 65-67 as allegedly being anticipated by Murad (U.S. Patent No. 6,630,163). Applicants respectfully disagree and traverse.

The Murad document mentions use of fruit extracts generally to treat a multitude of diseases, and mentions kiwi in a laundry list. However, Murad does not disclose hardy kiwifruit much less the hardy kiwi fruit extracts of the claimed invention. Generally, kiwi or kiwifruit denotes a fruit of *Actinidia deliciosa* (golden kiwi) or *Actinidia chinensis* (kiwi or green kiwi). (See, USDA, ARS, National Genetic Resources Program. *Germplasm Resources Information Network - (GRIN)* [Online Database]. National Germplasm Resources Laboratory, Beltsville, Maryland.  
URL: <http://www.ars-grin.gov/cgi-bin/npgs/html/splist.pl?149> (25 April 2007))

Although they are included in the same *Actinidiaceae* family and their tastes are similar, hardy kiwifruits are very different from the general kiwi or kiwifruit one finds commercially. The hardy kiwifruit (e.g., *Actinidia arguta* and *Actinidia kolomikta*) is native to northeastern Asia, while its commercially available cousin (*A. chinensis* and *A. deliciosa*) is native to southern China. Moreover, the commercially available kiwi and the hardy kiwi differ physically. Commercially available kiwifruits (*A. chinensis* and *A. deliciosa*) have a size and shape similar to a large hen's egg with a fuzzy, brown exterior. Hardy kiwifruit (*A. arguta* and *A. kolomikta*) and similar species on the other hand are much smaller than commercially available kiwifruit. Hardy kiwifruit has a size similar to a grape and has smooth edible skin.

Furthermore, extracts from hardy kiwifruits are superior to extracts from general kiwifruits (*A. deliciosa*) in modulating immune responses. These unexpected results clearly delineate hardy kiwifruits and their extracts from the more general fruit extracts mentioned by Murad.

Nevertheless, in order to advance prosecution, Applicants have amended claim 38 to recite only extracts of hardy kiwifruit species: *Actinidia arguta*, *Actinidia kolomikta* and *Actinidia polygama*.

In addition to the fact that Murad does not disclose hardy kiwifruit extracts of the claimed invention, it also does not disclose treatment of non-dermatological diseases much less the treatment of non-dermatological diseases with hardy kiwifruit extracts. Murad does not teach treatment of any of the conditions of new claims 113-145 with hardy kiwifruit extracts.

Applicants therefore respectfully request that the Examiner withdraw the outstanding rejection under 35 U.S.C. 102.

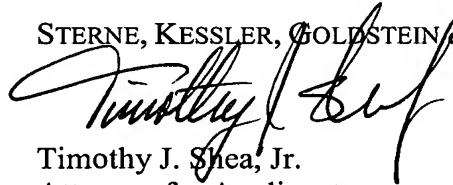
***Conclusion***

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Timothy J. Shea, Jr.  
Attorney for Applicants  
Registration No. 41,306

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1100 New York Avenue, N.W.  
Washington, D.C. 20005-3934  
(202) 371-2600

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